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Obesity

Translation of a Behavioral Weight Loss Intervention for Mid-life, Low-Income Women in Local Health Departments

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Objective: To translate a behavioral weight loss intervention for mid-life, low-income women in real world settings.

Design and Methods: In this pragmatic clinical trial, we randomly selected six North Carolina county health departments and trained their current staff to deliver a 16-session evidence-based behavioral weight loss intervention (special intervention, SI). SI weight loss outcomes were compared to a delayed intervention (DI) control group.

Results: Of 432 women expressing interest, 189 completed baseline measures and were randomized within health departments to SI ($N = 126$) or DI ($N = 63$). At baseline, average age was 51 years, 53% were African American, mean weight was 100 kg, and BMI averaged 37 kg/m^2. A total of 96 (76%) SI and 55 (87%) DI participants returned for 5-month follow-up measures. The crude weight change was −3.1 kg in the SI and −0.4 kg in the DI group, for a difference of 2.8 kg (95% CI 1.4 to 4.1, $p = 0.0001$). Diet quality and physical activity improved significantly more in the SI group, and estimated intervention costs were $327 per participant.

Conclusion: This pragmatic short-term weight loss intervention targeted to low-income mid-life women yielded meaningful weight loss when translated to the county health department setting.

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Introduction

Recent studies of weight trends among US adults indicated low-income women, as a subgroup, have the highest rates of overweight and obesity (1-3). In North Carolina, which has the nation's 14th highest adult obesity rate (2), these weight trends are similar: the state's top obesity rates are found in low-income women and midlife adults (45-64 years of age) (3). As a result, midlife low-income women are at high risk for obesity-related chronic diseases, including diabetes and cardiovascular disease (4). Achieving reductions in obesity rates for midlife low-income women is, therefore, of critical importance in lowering the high obesity-related social and healthcare costs, morbidity, and mortality.

Efficacy trials indicate that behavioral weight management interventions can result in clinically meaningful weight loss (5,6). Scant evidence is available, however, on how to adapt these proven interventions to real world settings and diverse population groups (7). Pragmatic implementation research (8-10), which is designed to determine the effects of an intervention delivered under usual conditions and help users choose between available options, is needed to ensure that efficacious weight management interventions become more widely used and available, especially in practice settings that serve low-income populations at high risk for obesity. Such pragmatic implementation research (11) shares features with practical clinical trials (12), which provide information for decision-makers on how an intervention works in representative practice settings, including pragmatic considerations of cost and participation. This type of research is vitally important, as resource-poor public health settings often differ substantially from the highly resourced settings that typically are used to assess an intervention's efficacy in randomized controlled trials (7).

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As there is a dearth of pragmatic implementation research that addresses weight management in low income populations, our project is very timely in its evaluation of the process and outcomes of integrating from research into practice an evidence-based behavioral weight loss intervention (Weight-Wise II intervention) among midlife low-income women. Our dual process and outcome evaluations were guided by the RE-AIM (Reach, Effectiveness or efficacy, Adoption, Implementation, and Maintenance) framework (13), which focuses on five dimensions of intervention success and sustainability, thereby seeking to enhance the quality, speed, and public health impact of efforts to translate research into practice. In this article, we only describe the outcome evaluation of the Weight-Wise II intervention. Evaluations of the Weight-Wise II implementation process will be reported separately.

Methods and Procedures

Study Design

The study included two phases: an assessment and preparation period (Phase I) and a randomized controlled trial (Phase II). Phase I, which focused on identifying and preparing study sites to deliver the intervention, has been described in detail (14). The primary aim of Phase II, depicted in **Figure 1**, was to assess the effectiveness of a 16 week group-based weight loss intervention (the Weight-Wise II intervention (14), hereafter called the special intervention (SI), at achieving weight loss when implemented by health department staff in community settings. Other secondary aims of Phase II included assessment of the intervention's effect on blood pressure, lifestyle behaviors, and psychosocial outcomes, and an evaluation of implementation costs.

The randomized trial of this pragmatic implementation study was limited to 5 months. Our rationale for 5 months duration was that the intervention would yield clinically significant weight loss (15), although not yet confirmed by this type of research. After the trial, participants in the intensive weight lost group received a pilot weight loss maintenance intervention and those in the wait-listed control (or delayed intervention [DI]) group received an abbreviated 10-week weight loss program. The University of North Carolina at Chapel Hill (UNC) Public Health-Nursing Institutional Review Board approved and monitored the study.

Study Sites and Staff Training

The weight loss intervention evaluated in this study was designed for delivery by staff in county health departments and other low-resourced settings, such as federally qualified community health centers. To randomly select health departments for this study, we used an optimal probability sampling protocol described elsewhere (14,16). In brief, health departments representing 81 of North Carolina's 100 counties were invited to take part in this study based on location and other county characteristics. Of these, 30 were eligible and interested, and 6 were chosen at random to participate. Selected sites were similar to eligible sites in terms of county demographics and health department characteristics. Once selected, each health department was asked to identify an interventionist (dietitian, nurse, or health educator) and an assistant to administer this program at the health department.

Prior to enrolling study participants, staff at participating health departments received training on informed consent and confidentiality, participant recruitment, and data collection. The health department interventionists and assistants also received training from the UNC research staff on how to deliver the intervention. Background information on nutrition and physical activity were provided in two on-line training modules (1 hour each) completed by interventionists before the face-to-face training on lifestyle behavior changes to promote weight loss. The interventionists were trained on behavior change strategies, motivational interviewing principles, and intervention implementation and data collection procedures, during 4 weekly group-based sessions, each lasting 6 hours. Interventionists received continuing education credits for completing the training program.

Study Participants, Baseline Measures, and Randomization

The intervention staff at each health department recruited study participants. UNC research staff developed five recruitment templates for study sites to use in publicizing the study to prospective health department patients and to the community at large. The templates included a study brochure, flyer or poster, newspaper ad, public service announcement, and a letter for health department patients. Each template briefly described the study, its duration, and inclusion/exclusion criteria. Study sites used the templates most appropriate for their setting.

Women between 40 and 64 years who met the following inclusion criteria were eligible for study participation: (1) body mass index (BMI) between 27.5 and 45 kg/m^2, inclusive; (2) willing to lose 5% or more of initial body weight and follow recommendations for healthy dietary and physical activity patterns; (3) English-speaking; (4) willing to give informed consent; and (5) household income less than or equal to 250% of federal poverty guidelines. Women interested in the study were asked to call the health department and complete a pre-screening phone interview to assess eligibility. The interventionist or assistant at each study site conducted these 5-10 minute phone interviews, with verbal informed consent for the interview obtained at the outset. After pre-screening for eligibility, women were screened for motivation to participate in an intense intervention. Screening for motivation included questions about: reasons for wanting to lose weight; confidence in ability to change behaviors related to self-monitoring, physical activity, and intake of fruits and vegetables; family support; and barriers to attending sessions. The screening call ended with scheduling of an enrollment visit appointment at their local health department for eligible women expressing both interest and motivation to lose weight.

The interventionist and assistant at each site conducted the enrollment visit. After obtaining written informed consent, baseline data were collected. Questions adapted from the Phyiscal Activity Readiness Questionnaire (PAR-Q) (17) were also adminstered to determine if participants could safely engage in moderate-intensity physical activity. Participants with a positive PAR-Q were required to obtain written clearance from their clinician prior to participating in the physical activity component of the group-based intervention sessions. Written permission to participate in the study and to engage in moderate-intensity physical activity was also required from clinicians of participants who had a myocardial infarction or stroke within the past 6 months.

Each study site was asked to enroll 40 women during an 8-week period. After collecting baseline data on all participants at the health

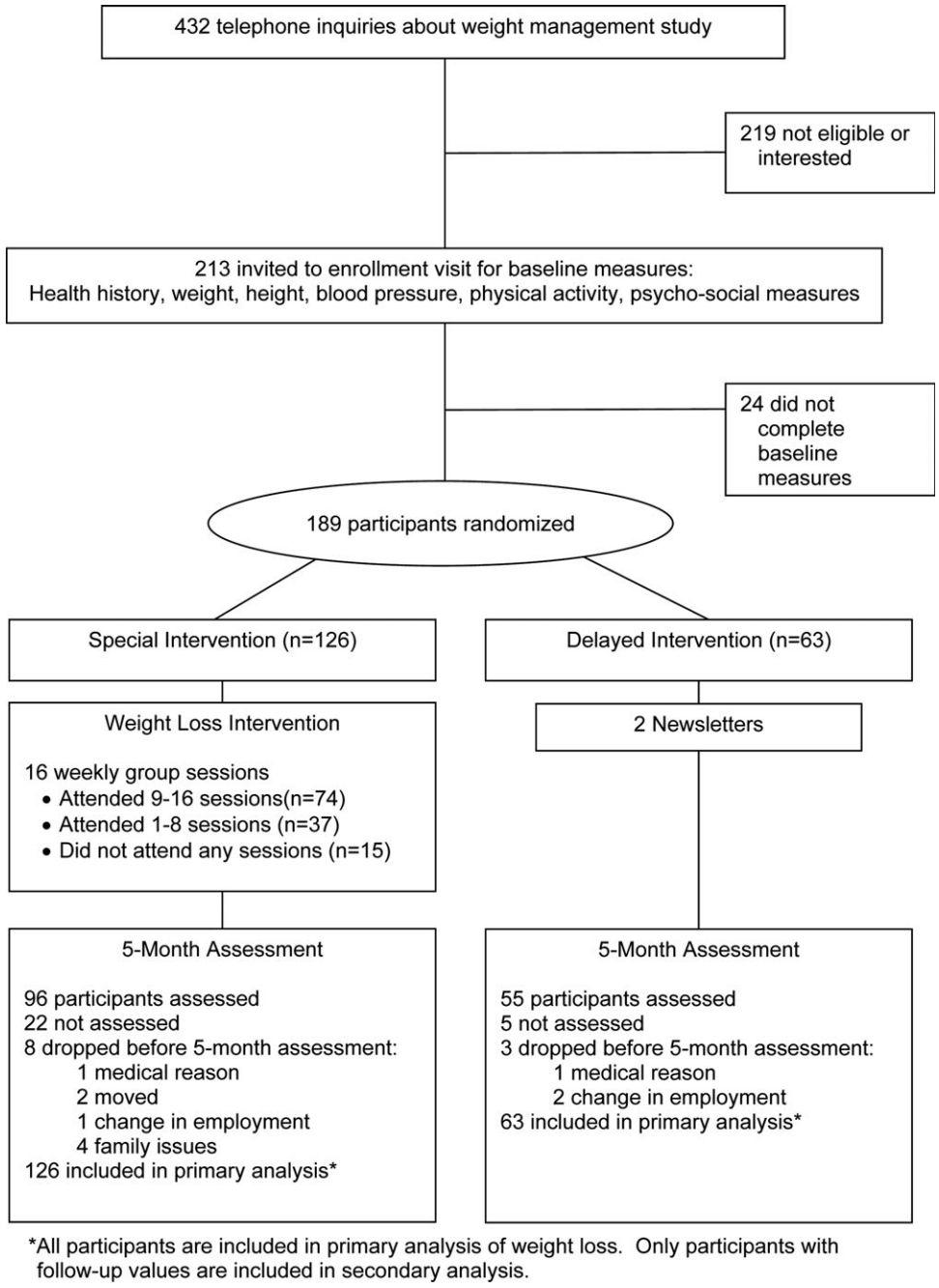

FIGURE 1 Flow of Weight-Wise II Participants through Trial.

department, participants at that site were allocated randomly by a computer program to the SI or to the DI in a 2 to 1 ratio. The 2 to 1 ratio was selected to increase the sample in the SI and subsequently in the 12-month pilot weight loss maintenance study.

Intervention

The weight loss intervention for this study (Weight-Wise II) has previously been described in detail (14,18). In brief, the intervention was adapted from three evidence-based behavioral weight loss interventions (19-21) to fit the social and cultural needs of low-income midlife women. The study goal for weight loss was 10 pounds, to be achieved through caloric restrictions (daily caloric levels of no less than 1,200 calories) and 150 minutes per week of moderate intensity physical activity to produce a weight loss of 1-2 pounds per week.

The intervention included 16 weekly group sessions, each lasting approximately 2 hours and including 10-15 participants. Sessions began with monitoring of weight, then followed the basic format

used in the Weight Loss Maintenance (20) and Weight-Wise (18) trials: participant check-in discussion (25 minutes); session topic (30 minutes); physical activity demonstration or food tasting (20 minutes); and goal-setting and action planning (15 minutes). Educational materials for the group sessions included session handouts and a participant manual (*A New Leaf … Healthy Choices for Living*) (22) which included weight loss, nutrition, and physical activity information. Each participant also received a calorie counter and diaries to record daily food intake, calories (optional), and physical activity minutes.

Each interventionist made site-specific decisions about how physical activity and food-related activities would be conducted and whether community partners or resources (e.g., dance exercise or yoga instructors) would be considered in delivering that session component. Participant incentives were also allowed as part of the group contacts. Funds were provided for a limited number of incentives, and each site determined how incentives would be delivered to participants (e.g., weekly at each session, periodically based on points earned for reaching behavioral goals, or a combination of both). Small weekly incentives included items such as pedometers, measuring cups, or magnets. Larger incentives such as exercise DVDs, bathroom scales, and small grills, could be earned through the points system. For the DI participants, no educational materials about weight loss were provided during the waiting period, but two newsletters with general health information and Weight-Wise II program updates were mailed from the research office during months 2 and 4 of the 16-week intervention.

Data Collection

Baseline and follow-up data were collected through in-person visits, by telephone, and by accelerometers participants wore. At baseline, weight and height were measured without shoes using an electronic scale (Seca 770; Seca, Columbia, MD) and portable stadiometer (Schorr Productions, Olney, MD). Two measures were obtained and averaged for height and weight. Staff not masked to participants' treatment condition recorded weights at each intervention group session; for these assessments, participants were weighed once. Outcome weights, assessed during the week of the 16th intervention visit, were measured in duplicate and averaged for both SI and DI participants by trained staff masked to the participants' group assignment. The other in-person outcome measures were assessed at a measurement visit post-intervention (approximately 5 months after randomization). Blood pressure was measured (after the participant was seated for 5 minutes) with an Omron HEM-907XL automated blood pressure monitor (Omron Healthcare, Bannockburn, IL, USA). Three blood pressure measurements were obtained at 60 second intervals and averaged.

Physical activity was assessed by questionnaire and by and ActiGraph accelerometer (model GT1M, Pensacola, FL, USA), a small uniaxial accelerometer attached to a belt and worn at waist level over the right hip (23). Participants were asked to wear the monitor for the next 7 days at baseline and follow-up, and then return it using a postage-paid mailer. Monitor data were downloaded to a computer and daily activity variables were derived using cut points for accelerometer activity counts that corresponded to sedentary ($\leq$99), light (100-2,019), moderate (2,020-5,999), and vigorous intensity ($\geq$6,000) physical activity (24). Participants' accelerometer data were included in the analysis if they wore the monitor for at least 10 hours during 4 days of monitoring. Non-wear time was determined by assessing bouts of 60 consecutive minutes of zero activity.

About 1-3 weeks after the baseline in-person measurement visit and after the final SI group session, participants were contacted by phone and administered a series of previously tested or validated questionnaires to assess: fruit and vegetable intake (25), physical activity (adaptation of the RESIDE questionnaire) (26), obesity and weight loss quality of life (OWLQOL) (27), and depression symptoms (PHQ-8) (28). Follow-up questionnaires were administered by an interviewer who was masked to participants' study group assignment until administration of the final questionnaire addressing study acceptability. At each measurement visit, participants received a $10 gift card and another $20 gift card for wearing the physical activity monitor. They also received a $10 gift card for completing each of the data collection phone calls.

Following the intervention, we estimated the costs of intervention delivery and collected data from the intervention staff about post-study program implementation plans. To estimate the costs of delivering the study intervention, we applied the methods used in the Weight-Wise I study (29). With this approach, both direct and indirect costs are included in the total cost. Direct costs include those required to replicate the program (e.g., personnel costs for training and program delivery, and participant materials); indirect costs include overhead costs (e.g., space rental or agency stipends). The cost per participant was calculated as the ratio of total intervention costs to the number of SI participants. Additionally, we used structured interviews to gather information from the intervention staff about post-study program implementation plans. All interviews were conducted by trained interviewers not affiliated with the study.

Sample Size and Statistical Analysis

Sample size for the primary study outcome (the comparison of weight change between SI and DI groups at 5 month follow-up), was based on the following assumptions: simple randomization within health departments; a two-sided test of significance at $\alpha = 0.05$; 80% power; a difference in mean change in weight between groups of 2.6 kg; and standard deviation of weight change =3.7 kg based on our Weight Wise I Study (18). Allowing for an anticipated 20% attrition rate, a sample size of 40 participants per arm was required. In order to assess important secondary outcomes and have an adequate sample size for the pilot weight loss maintenance program, our goal was to enroll a larger total sample of 240 participants.

Baseline characteristics of participants have been summarized elsewhere (14). Differences in these characteristics between groups were compared using chi-square for categorical variables and *t*-tests for continuous variables. Similarly, baseline characteristics of those who dropped out were compared to those who remained, to assess whether or not they were similar. The primary outcome analysis to test the effectiveness of the 16-week weight loss intervention was conducted using a simple *t*-test under the intent-to-treat principle, with various imputation approaches. Imputation methods included: (1) last observation carried forward; (2) missing follow-up weights imputed with zero change from baseline but with the same sample variance of those who completed the study; and (3) multiple imputations using PROC MI (50 set of datasets imputed) and combined using PROC MI ANALYZE (30). The

results from these analyses were compared to the result from analyses of those who completed the study (and provided follow-up weight data).

Additional analyses were conducted using two multivariable regression models: (1) an analysis of covariance (ANCOVA) model adjusting for baseline weight and health departments and (2) a multivariable model that included additional variables distributed differently between intervention and control groups at baseline or between those with follow-up data and those who did not return for follow-up. Furthermore, we fitted a selection model (31) that allows the weight at follow-up (primary outcome) to be missing, but not-at-random. The selection model consists of two components: the measurement component and the dropout component. Both components included the same variables as the multivariable model noted above. In addition, we also conducted a series of sensitivity analyses assuming the following missing data patterns: those dropped out from SI were assumed to gain 0, 1, 2, 3, 4, or 5 kg compared to 0-kg gain in DI, and to have the same standard deviation of weight loss as those who remained in the study. The analyses for secondary outcomes were performed using *t*-tests, ANCOVAs, and multivariable regression models with data from those who completed the study. SAS software (Version 9.2, SAS Institute, Cary, NC, USA) was used for all analyses.

Results

Each of the six study sites employed at least four different recruitment strategies to publicize the Weight-Wise II study in their communities. As depicted in Figure 1, of 432 women who called to express interest in the study, 219 (51%) did not meet entry criteria or were not interested in the study after learning more about it. Of the 213 (49%) women who were eligible and interested, 189 (89%) completed required baseline measures and were enrolled. The number of participants per study site ranged from 21 to 40, with health departments in smaller counties enrolling fewer participants. Interventionists included a nurse, dietitian, and four health educators. On average, interventionists had 10 years of public health experience, and worked at the current agency for 9 years; only one had formal training in adult weight management (16).

Table 1 depicts selected baseline participant characteristics. Overall, the intervention groups were similar, except that moderate-intensity physical activity assessed by accelerometry and prior participation in a structured weight loss program were higher among SI as compared to DI participants. The average age of participants was 51 years with 53% self-identified as non-Hispanic African American, 51% currently employed, 20% with household income less than $10,000 per year, and 43% without health insurance. Based on self-report, 51% had high blood pressure, 40% high cholesterol, 20% diabetes, and 15% known coronary heart disease. The mean weight of participants was 100 kg, with a mean BMI of 37 kg/m^2; systolic and diastolic blood pressure averaged 126 and 83 mm Hg, respectively. On average, participants consumed 3.9 servings of fruits and vegetables per day and engaged in 11.3 minutes/day of moderate intensity physical activity (as assessed by accelerometer).

Follow-up for end-of-study weight assessment was 76% (96/126) for SI participants and 87% (55/63) for the DI group. Participants who did not return for follow-up were more likely to be younger, to take blood pressure medication, to live with fewer adults, and to be African American (data not shown, $p \leq 0.05$). For the analysis of the primary outcome (the comparison of weight change between groups), we used imputed values for those missing follow-up weights at 5 months. Using baseline weight carried forward for missing data at follow-up, the crude weight change was −2.8 kg in the SI group and −0.4 kg in the DI group, for a difference of 2.4 kg (95% CI 1.1-3.8, $p = 0.0004$). Using last observation carried forward for missing data at follow-up, the crude weight change was −3.1 kg in the SI group and −0.4 kg in the DI group, for a difference of 2.8 kg (95% CI 1.4-4.1, $p = 0.0001$). In a model that adjusted for baseline weight, health departments, prior participation in weight loss programs and variables that differed between those who returned for the 5-month follow-up weight and those who did not (age, blood pressure medication, number of adults in household, and race), the difference was 2.5 kg (95% CI 1.3-3.9, $p = 0.0004$). Using additional methods of imputation, including models for follow-up data not missing at random, the results were similar (data not shown).

Crude and adjusted study outcomes for those who completed follow-up assessments at 5 months are shown in **Table** 2. SI participants had an average weight loss of 3.7 kg (4% of initial body weight) versus 0.4 kg for the DI group, with an adjusted mean difference of 3.3 kg (95% CI 1.7-4.9, $p < 0.0001$). In addition, 40 (42%) SI participants lost 5% or more of their baseline body weight compared to 5 (9%) in the DI group. At follow-up, systolic and diastolic blood pressure was reduced modestly in both groups, but the difference was not statistically significant. SI participants reported a significant increase of 2.0 grams/day in fiber intake, compared to an increase of 0.2 in the DI group ($p = 0.0004$). The adjusted difference of −1.8 grams/day marginally reached statistical significance (95% CI −2.98 to −0.62, $p = 0.05$).

Self-reported moderate-intensity physical activity increased 13.9 minutes per day among SI participants compared to 1.5 minutes for the DI group (difference −15.1, 95% CI −23.3 to −6.9, $p = 0.0004$). For accelerometry-determined moderate-intensity physical activity, 154 participants (103 SI, 51 DI) at baseline and 114 participants ($N = 74$ SI, $N = 40$ DI) at follow-up met the minimal accelerometer wearing time of at least 10 hours on 4 days of the monitored week. Only 105 (56%) of the total study sample met these criteria both at baseline and follow-up ($N = 68$ SI, $N = 37$ DI). Among this group, there was a 1.9 minutes/ day increase in the SI group, compared to a 1.3 minute per day decrease in the DI group, with an adjusted difference between groups of −5.4 minutes per day (95% CI −10.5 to −0.3, $p = 0.04$).

Two key psychosocial outcomes were evaluated in this study: obesity and weight loss-related quality of life (OWLQOL) and depression. For OWLQOL, a higher score indicates improved quality of life, and for the depression scale, a lower score suggests less depression symptoms. At follow-up, the OWLQOL score increased by 12.2 among SI participants and 6.6 for the DI group, yielding an adjusted difference of −7.1 (95% CI −12.0 to −2.2 $p = 0.006$). The depression symptoms score decreased 1.9 among SI participants and 0.9 for the DI group, yielding an adjusted difference of 1.2 (95% CI −0.2 to 2.6, $p = 0.09$). Moreover, among SI participants, improvement in the depression score was significantly ($p = 0.01$) associated with more group sessions attended.

TABLE 1 Baseline participant characteristics[a]

Characteristic	Special Intervention ($n = 126$)	Delayed Intervention ($n = 63$)	p-value
Demographics			
Age, years	50.8 (0.7)	51.8 (0.8)	0.35
Race/ethnicity			
Non-Hispanic Black/African American, *N* (%)	67 (53)	33 (52)	0.92
Other[b], *N* (%)	59 (47)	30 (48)	0.92
Educational achievement, years	13.0 (0.2)	13.0 (0.2)	0.87
Currently employed, *N* (%)	70 (56)	26 (41)	0.06
Adults (≥18 y) in household	1.8 (0.1)	1.9 (0.1)	0.29
Annual household income <$10,000, *N* (%)	25 (21)	11 (18)	0.69
Lack health insurance, *N* (%)	51 (40)	30 (48)	0.35
Risk Factors for Coronary Heart Disease			
Currently cigarette smoker, *N* (%)	18 (14)	11 (17)	0.58
Diagnosed with high blood pressure, *N* (%)	64 (51)	32 (51)	1.00
Treated with blood pressure medication, *N* (%)	58 (46)	30 (48)	0.76
Diagnosed with high blood cholesterol, *N* (%)	47 (38)	28 (45)	0.51
Treated with cholesterol medication, *N* (%)	34 (27)	22 (35)	0.23
Diagnosed with diabetes, *N* (%)	21 (17)	16 (25)	0.31
Treated with diabetes medication, *N* (%)	18 (14)	12 (19)	0.65
Positive family history for CHD, *N* (%)	40 (32)	12 (19)	0.07
Known CHD, *N* (%)	18 (14)	11 (17)	0.58
Body weight and blood pressure			
Weight (kg)	100.1 (1.3)	98.8 (1.5)	0.56
Body mass index (kg/m^2)	37.6 (0.4)	36.7 (0.6)	0.22
Systolic blood pressure (mm Hg)	125.5 (1.5)	127.5 (2.9)	0.54
Diastolic blood pressure (mm Hg)	83.4 (1.0)	82.0 (1.7)	0.43
Diet and physical activity			
Took part in prior structured weight loss program during prior 2 years	15 (12)	2 (3)	0.05
Fruit-vegetable-fiber screener			
Fruit-vegetable servings per day	3.9 (0.2)	3.9 (0.2)	0.85
Dietary Fiber (grams per day)	12.1 (0.4)	12.1 (0.6)	0.86
Physical Activity Assessment:			
Steps/day, accelerometer[d]	5,515 (207)	4,862 (233)	0.05
Minutes/day of moderate physical activity, questionnaire[c]	20.1 (2.6)	19.0 (3.2)	0.79
Minutes/day of moderate physical activity, accelerometer[d]	12.4 (1.1)	8.9 (1.1)	0.02

[a]Data are expressed as mean (SE) unless otherwise indicated.
[b]83 Non-Hispanic White; 2 Hispanic White; 2 American Indian/Alaska Native; 1 Black/African American and American Indian/Alaska Native; 1 unknown
[c]Assessed by modified RESIDE's Neighborhood Physical Activity Questionnaire (26).
[d]Assessed by ActiGraph GT1M accelerometer (Pensacola, FL, USA); Total $n = 154$, Special Intervention $n = 103$, Delayed Intervention $n = 51$.
Abbreviations: *N*, number; CHD, coronary heart disease.

Figure 2 shows weight change for SI participants (last weight brought forward for missing values) assessed over the course of the intervention by attendance at group sessions. Weight loss was greatest for those attending all 16 sessions (−7.1 kg; $N = 11$), somewhat less for those attending 9 or more sessions (−4.7 kg; $N = 74$), and minimal loss for those attending no sessions ($N = 15$) or less than 9 (−0.7 kg; $N = 37$). In addition, those attending all sessions weighed substantially less at baseline.

Table 3 shows the number of intervention visits and weight loss (without imputation) by health department. At 5 of the 6 study sites, the average number of intervention visits ranged from 9.4 to 10.6, and mean weight loss was 3.2-5.4 kg. The difference in weight loss between SI and DI participants ranged from 2.6 to 4.1 kg. In a multivariable model, with change in weight at 5 months as the dependent variable and covariates of baseline weight, study site, prior participation in weight loss program, age, taking blood pressure medication, number of other adults in household, and race, we found weight change was significantly associated with baseline weight ($p < 0.0001$), and race ($p = 0.005$), with study site reaching marginal statistical significance ($p = 0.05$). Greater weight loss was associated with lower baseline weight and non-African American race.

TABLE 2 Study outcomes: change from baseline to 5 months and differences between groups (crude and adjusted means)[a]

	Special Intervention (SI) ($N = 126$)		Delayed Intervention (DI) ($N = 63$)		Difference (DI minus SI)			
Outcome[b]	No. Assessed	Mean (SE)	No. Assessed	Mean (SE)	Crude Mean (SE)	Adjusted Mean (SE)	Adjusted 95% CI	*Adjusted P-value*
Weight, kg,	96	−3.7 (0.49)	55	−0.4 (0.60)	3.3 (0.79)	3.3 (0.80)	1.7 to 4.9	<0.0001
Systolic blood pressure, mm Hg	92	−4.5 (1.65)	53	−4.2 (2.86)	0.3 (3.07)	1.2 (2.55)	−3.8 to 6.2	0.65
Diastolic blood pressure, mm Hg	92	−3.4 (1.12)	53	−2.4 (1.48)	1.0 (1.86)	0.0 (1.74)	−3.4 to 3.4	0.98
Fruit and vegetables servings per day	100	0.5 (0.15)	57	0.2 (0.17)	−0.4 (0.24)	−0.4(0.21)	−0.81 to 0.01	0.08
Dietary fiber, gms per day	100	2.0 (0.41)	57	0.2 (0.45)	−1.8 (0.64)	−1.8 (0.60)	−2.98 to −0.62	0.004
Steps per day (accelerometer)	68	605 (243.5)	37	−202 (234.5)	−807 (373.0)	−1,071 (368.7)	348 to 1,793	0.005
Minutes/day of moderate physical activity (self-report)	100	13.9 (3.16)	57	1.5 (4.44)	−12.4 (5.36)	−15.1 (4.17)	−23.3 to −6.9	0.0004
Minutes/day of moderate physical activity (accelerometer)	68	1.9 (1.75)	37	−1.3 (1.21)	−3.2 (2.53)	−5.4 (2.59)	−10.5 to −0.3	0.04
Obesity and Weight Loss Quality of Life	100	12.2 (1.63)	57	6.6 (2.02)	−5.6 (2.65)	−7.1 (2.52)	−12.0 to −2.2	0.006
Depression Score	100	−1.9 (0.42)	57	−0.9 (0.57)	1.0 (0.70)	1.2 (0.69)	−0.2 to 2.6	0.09

[a]Adjusted for: Study site and baseline weight, moderate intensity physical activity, prior participation in weight loss program, age, taking blood pressure medication, number of other adults in household, and race.
[b]A negative value indicates a decrease compared to baseline; positive value indicates an increase.

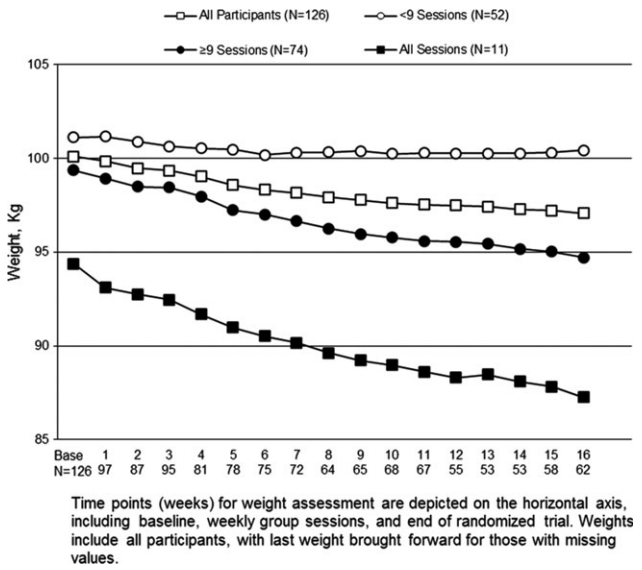

FIGURE 2 Weight Change among Special Intervention Participants by Attendance at Weekly Group Sessions.

Other areas assessed in this implementation research included costs of delivering the intervention, participant acceptability of the program, and interventionists' views on their health department continuing to provide Weight-Wise programing after study completion. The total cost (direct and indirect) associated with delivering the 16-week program at 6 sites was $41,189, resulting in a cost of $327 per participant. Acceptability surveys were completed by 80% (101/126) of SI participants. Of these, 82 (81%) were very satisfied and 9 (9%) were satisfied with the program. In addition, 87 (86%) thought the interactions between women in the group were very good, 91 (90%) thought the health counselor was very good, and 86 (86%) thought the session materials were very good. When asked about the number of sessions, 60 (59%) indicated the number was just right, 33 (33%) thought the number was not enough, and 5 (5%) indicated there were too many sessions.

At the end of the study period, we also interviewed the intervention staff to identify their agencies' plans for future adoption of the Weight-Wise program (both as a means of providing weight loss services or using the program materials in other ways). Intervention staff from 5 of the 6 sites (83%) reported that there were plans being made at their agencies for future implementation of the Weight-Wise program. These plans included offering the full program or modified versions of it to health department or county employees (three of six sites), or implementing the program at a local church (one site). Intervention staff at each site also mentioned that they planned to use Weight-Wise program materials in new programs or services, and had already added them to existing program materials, or shared them with other health department staff.

During this randomized trial, 16 participants (8 in each study group) reported health concerns that were considered unanticipated problems or adverse events. All of these events were determined unlikely related to the research, except for 1 in a SI participant who had pain and swelling in a lower extremity and was advised by her physician to restrict ambulation. It was unknown if this event was related to physical activity recommended by the intervention.

Following the randomized trial (after follow-up measurements), participants in the DI group received a 10-session program using content from the 16-week program. With follow-up weights from 39 participants (71% of participants ($n = 55$) returning for post-trial data collection), the average weight loss was 2.4 kg ($p < 0.001$), with a range of 0.9-4.7 kg.

Discussion

In this pragmatic implementation trial, we randomly selected a representative sample of health departments, and trained interventionists from their current workforce who then delivered an evidence-based weight loss intervention to a sample of overweight and obese low-income, mid-life women who are typical of health department patients and under-represented in published weight loss trials (14). Among SI participants who returned for the 5-month follow-up visit, the mean weight loss was 3.7 kg, which is similar to that typically noted in interventions evaluated in mostly white and higher income

TABLE 3 Mean number of study intervention sessions attended and change in weight by study site

	Special intervention (SI) ($n = 126$)			Delayed intervention (DI) ($n = 63$)		Difference (DI minus SI)	
Study site	No. assessed	Mean session attended	Mean change in weight (kg)	No. assessed	Mean change in weight (kg)[a]	Mean	*p*
1	18/27	10.4	−4.8 (0.90)	11/13	−1.2 (1.12)	3.6	0.0225
2	18/22	10.6	−3.2 (1.17)	10/11	0.9 (1.08)	4.1	0.0340
3	15/23	6.1	−1.2 (1.05)	9/11	1.4 (1.17)	2.6	0.1440
4	22/24	10.3	−3.9 (0.63)	11/12	−1.3 (0.93)	2.6	0.0277
5	12/16	9.9	−5.4 (1.85)	8/9	−1.9 (2.61)	3.5	0.2992
6	11/14	9.4	−3.9 (1.86)	6/7	−0.3 (1.52)	3.6	0.2490

[a]Change in weight during the waiting period for DI participants.

populations, and in academic settings (15,32). Moreover, 42% of SI participants who returned at 5-month follow-up lost 5% or more of their initial body weight, a proportion similar to that achieved in the enhanced intervention groups of 2 recently published weight loss trials conducted in primary care practices, but utilizing specially trained interventionists (33,34). Our findings suggest effective implementation of an evidence-based intervention in this sample of randomly selected health departments. Moreover, these findings are noteworthy because: (1) so few weight management studies have been conducted in low-income populations (35); (2) unlike many weight loss studies (20,36), this study had few exclusion criteria; and (3) very few translational research studies that specifically address weight loss have been published.

In addition to weight loss, SI participants reported improved dietary quality including intake of significantly more fiber and more fruits and vegetables than the DI group. Furthermore, participants in the SI group reported more moderate intensity physical activity (12.4 minutes/day) than the DI group and recorded more moderate intensity physical activity (3.2 minutes) as assessed by accelerometer, with both measures of physical activity statistically significant when comparing treatment arms of the study. Of note, systolic and diastolic blood pressure was reduced modestly in both groups, but the difference between groups was not significant.

We also assessed a limited set of important psychosocial outcomes, costs of intervention delivery, and acceptability of the intervention. Importantly, SI participants reported a substantial and statistically significant improved score on the obesity and weight loss quality of life measure (27). In addition, there was a trend towards less depression symptoms among SI participants and improvement in the depression score was associated with more group sessions attended. From our assessment of intervention costs, the estimated $327 per participant for delivering Weight-Wise II at multiple sites compares favorably with the $200-1,400 per person costs of other weight loss interventions (37,38). This estimate is slightly higher than that for Weight-Wise I ($242 per participant) (29), with the average cost per kilogram lost estimated at $88 (compared to $61 in Weight-Wise I). This higher cost is likely due to travel costs associated with the training of staff and the overhead costs for 6 sites (compared to 1 site in Weight-Wise I).

Furthermore, Weight-Wise II was very well received by participants and it is noteworthy that one third of those completing the acceptability questionnaire thought that the number of group sessions was not enough. This level of participant acceptability and interest in intense weight management services is a welcome contrast to the commonly cited barrier of providers viewing patients as not interested in weight management (39,40). Indeed, five of the six interventionists in this study felt at the beginning of the trial that the greatest barrier to implementing a weight management program at their respective site was a perceived lack of interest by eligible clients (14). What may have been different with promoting this weight loss program was the emphasis placed on the proven effectiveness of the program, its cost (free) compared to commercial weight loss programs, having multiple opportunities to attend weekly sessions, and the value of losing weight with a group of women.

Strengths of this study include its focus on an underserved, low-income and high-risk population and its design as a real world pragmatic implementation research project. In addition, the intervention was adopted from evidence-based weight loss programs and included a dietary pattern consistent with current recommendations to reduce cardiovascular disease (with a focus on fat and carbohydrate quality). Moreover, we selected participating health departments randomly and trained the existing health department staff to deliver the intervention. This approach enhances the generalizability of study results. We also encouraged the health department interventionists to take advantage of local resources that could help facilitate weight loss. Additionally, our approach to implementing this study with health department staff as ''research partners'' helped to avoid a number of common challenges. We consulted with staff before and during study implementation, which allowed for timely discussion of issues and effective problem-solving.

Limitations of this study are worth noting. The most important is the short duration of the study. However, given our expectation that the intervention would result in weight loss, we wanted to minimize the time that the DI group received no intervention. Furthermore, those in the SI group were invited to enter a pilot maintenance of weight loss study, whose results will be reported separately. As this study was conducted in one region of the country where the public health system is organized into county health departments that typically serve low-income women and have health counselors on staff, this model of delivering a weight loss intervention may or may not be generalizable to other regions of the country. Additionally, our study was not designed to impact how many health departments delivered the Weight-Wise II program after the study intervention period. This measure of adoption is, however, important to the assessment of long-term feasibility of such programming in real world settings. Even though our exit interviews with the intervention staff showed that plans for future program implementation were being discussed, final decisions about program adoption would not be made by these staff and we did not structure our preparation phase for this study to include discussions with decision-makers about program adoption.

Conclusion

Our evidence-based weight loss intervention was successfully translated for implementation in real world settings. Six health departments chosen at random, that enrolled high risk and hard-to-reach overweight participants, were effective in producing substantial short-term weight loss, similar in amount to many efficacy trials conducted by trained research staff in academic settings. In addition, the intervention was associated with improved diet quality, a modest increase in physical activity, and improved weight-related quality of life. Furthermore, the cost of the intervention for weight loss was reasonable. Though future research should address maintenance of weight loss, our findings support implementation of this type of intervention in common community settings and provides important information to stakeholders and decision makers about the costs and benefits of this type of intervention. O

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